K041946

AUG 1 6 2004

XV. 510(k) Summary

Device Names:

ACON SPECTRUM Urine/Serum Pregnancy Test Device

Common Name:

Pregnancy Test Kit, Professionals

Medical Specialty:

Clinical Chemistry

Intended Use:

The ACON SPECTRUM Urine/Serum Pregnancy Test Device is for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine and serum to aid in the determination of pregnancy. It is for healthcare professionals only.

Device Description:

The test utilizes a combination of mouse monoclonal antibody conjugated with a proprietary dye-binding system and goat polyclonal antibody to qualitatively detect elevated levels of hCG in urine and serum samples. Test may be done by applying sample and observing visually for the formation of colored lines. After sample application, specimen migrates via capillary action along the components of the test. During migration, hCG molecule in the sample reacts with the monoclonal hCG antibodies-dye conjugate, and also reacts with the polyclonal hCG antibody striped down at the test region of the membrane to form an antibody-antigen-antibody-dye complex as a colored test line. Therefore, a colored line forms in the test (T) region indicates a **positive** result; while absence of this colored line indicates a **negative** result.

To serve as a procedural control, if the test has been performed properly, a RED colored zone in the control (C) region will always be cleared to expose a BLUE line, indicating adequate sample volume and proper wicking, regardless of the presence of hCG. The presence of the red dye or absence of the blue control line in the C region indicates that the test result is "**invalid**".

The ACON SPECTRUM Urine/Serum Pregnancy Test Device qualitatively detects hCG in urine or serum sample with a designated cutoff hCG concentration of 25 mIU/mL. The cutoff concentration of this test has been standardized to the World Health Organization Fourth International Standard for Chorionic Gonadotropin (NIBSC Code: 75/589). The addition of hLH (300 mIU/mL), hFSH (1,000 mIU/mL), and hTSH (1,000 μIU/mL) to negative (0 mIU/mL hCG)

and positive (25 mIU/mL hCG) urine and serum samples showed no interference in correctly read the expected test results.

Clinical Studies:

A clinical study was conducted in two sites in the U.S. by healthcare professionals with varying educational backgrounds and laboratory experience and demonstrated performance equivalency between the current and the new ACON hCG tests by professionals. A retrospective focus group study on reproducibility and precision also demonstrated high degree of correlation between the current and the new ACON hCG tests. The vast majority of the participants also found the ACON SPECTRUM Urine/Serum Pregnancy Test Device very easy to use, and that they have had no trouble understanding the labeling, reading the instructions, or interpreting the results.

Additional Laboratory Studies:

Additional laboratory study results on performance including specificity, interference substances, urinary pH, urinary specific gravity, dose hook effect, time flexibility, and volume flexibility studies are also included in this submission. These results indicate that the ACON SPECTRUM Urine/Serum Pregnancy Test Device is robust and will give accurate results under many adverse conditions.

Substantial Equivalency on Performance:

The overall performance data indicate that the ACON SPECTRUM Urine/Serum Pregnancy Test Device is safe, effective and substantially equivalent to the ACON hCG Urine/Serum One Step Pregnancy Test Device (K993065) legally sold on the U. S. market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 16 2004

Edward Tung, Ph.D.
Director of Regulatory Affairs
ACON Laboratories
4108 Sorrento Valley Blvd
San Diego, CA 92121

Re: k041946
Trade/Device Name: ACON SPECTRUM Urine/Serum Pregnancy Test Device
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: July 16, 2004
Received: July 19, 2004

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041946

Device Name: ACON SPECTRUM Urine/Serum Pregnancy Test Device

Indications For Use: The ACON SPECTRUM Urine/Serum Pregnancy Test Device is intended for the qualitative identification the elevated level of human Chorionic Gonadotropin (hCG) in urine and serum to aid in the determination of pregnancy. It is for healthcare professionals only.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041946